EXHIBIT 6

Case: *Charmaine Lloyd, et al. v. Johnson & Johnson, et al. (Plaintiff Eva Echeverria only).*
Case No.: BC628228 (JCCP No. 4872)
Motion(s): Motion in Limine re Laura Plunkett, Ph. D.
Hearing: June 26, 2017 and June 27, 2017

Tentative: Dr. Plunkett's opinions are permitted in part.

I. BACKGROUND

The background of this motion and legal standards applicable are set forth in the ruling regarding other general causation experts sought to be tendered by Plaintiff.

For purposes of this motion it is sufficient to note that Plaintiff seeks to call Laura Plunkett, Ph.D. ("Dr. Plunkett") to testify (1) to a reasonable degree of scientific certainty that talc can cause ovarian cancer when women use talc-based body powders on the genital area; (2) talc based powders should have had a warning label; and (3) defendants downplayed the risks and actively determined not to tell consumers of them. In two different filings defendant seeks to exclude Dr. Plunkett's testimony. The first set of arguments address her general causation opinions. A second set address her non-causation (legal) opinions.

The Court heard testimony from Dr. Plunkett on June 26 and 27, 2017 and now rules as follows.

II. DR. PLUNKETT'S QUALIFICATIONS

Dr. Plunkett received a Ph.D. in pharmacology from the University of Georgia, College of Pharmacy in 1984. Thereafter, she served as a Pharmacology Research Associate Training Fellow at the National Institute of General Medical Sciences, where her research focused on the role of various brain neurochemical systems involved in the control of the autonomic nervous system and cardiovascular function. At the conclusion of her fellowship in 1986, Dr. Plunkett joined the faculty at the College of Medicine, University of Arkansas for Medical Sciences, as an

Assistant Professor of Pharmacology and Toxicology. While there, she taught graduate courses in pharmacology, toxicology and neuroscience and conducted research in the areas of neuropharmacology and toxicology, as well as cardiovascular pharmacology and toxicology.

In 1989, Dr. Plunkett began work as a consultant at ENVIRON Corporation. At ENVIRON, Dr. Plunkett served clients in the areas of pharmacology, toxicology, risk assessment and regulatory strategy. She represents she focused specifically on issues involving products or processes regulated by the Food and Drug Administration ("FDA"). She testified that while at ENVIRON she was mentored by a former advisor to the FDA and learned the regulatory environment for various products. She also attended classes sponsored by the FDA and the Food, Drug, and Law Institute to learn about the regulatory environment.

In 1993, Dr. Plunkett became board-certified as a Diplomate of the American Board of Toxicology.

Dr. Plunkett left ENVIRON in 1997 and continued her consulting career as owner of Plunkett & Associates from 1997 to 2001, and then as President of Integrative Biostrategies LLC from 2001 to the present.

Over the course of her career as a consultant, Dr. Plunkett represents she has assisted clients with regulatory issues and strategies for their products, including designing preclinical and clinical studies for efficacy and safety, and assisting with labeling statements regarding a product's efficacy and safety.

Since 1982, Dr. Plunkett has authored or co-authored approximately thirty scientific publications, over forty abstracts and three book chapters. *See In re Seroquel Prods. Liab. Litig.*, 2009 U.S. Dist. LEXIS 115653, *150-153 (M.D. Fla. June 23, 2009)

III. SUMMARY OF ARGUMENTS

Defendants' argue first that Plunkett misapplied the "Bradford Hill" factors, which are used to demonstrate that an association between two events—here, talc use and ovarian cancer—is actually a causal relationship. Defendants identify the Bradford Hill factors as (1) strength of association; (2) consistency of association; (3) dose-response relationship; (4) biological plausibility; (5) temporal relationship; (6) consideration of alternative explanation; and (7) specificity. Defendants argue her analysis regarding the first four factors is insufficient. In addition, Defendants argue Plunkett is not qualified to testify that Defendants should have labeled their product to warn individuals such as Plaintiff that talc was dangerous because she lacks expertise regarding whether cosmetic companies should label their products, and because her opinions regarding what Defendants' internal reports informed them of, what conclusions they should have drawn from those reports, and what actions they should have taken as a result of those reports, are all conclusory and lack any specific methodology. Defendants also argue such statements are legal conclusions the jury can draw based on its lay understanding of the documents. Finally, Defendants argue Plunkett is not an expert on regulatory matters, and should therefore be prohibited from testifying regarding how the FDA works, or what the basis for FDA decisions may be.

In opposition, Plaintiff relies heavily on two unpublished federal cases, *In re Tylenol*, 2016 WL 4039329,[1] and *In re Gadolinium*, 2010 WL 1796334.[2] Plaintiff argues Plunkett is

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[1] Finding Dr. Plunkett qualified to opine regarding the warning label on Tylenol but finding that she cannot offer an opinion that the label itself was inadequate or that the defendants "failed to warn" consumers. *Terry v. McNeil-PPC, Inc. (In re Tylenol (Acetaminophen) Mktg., Sales Practices, & Prods. Liab. Litig.)*, 2016 U.S. Dist. LEXIS 99175, fn. 25 (E.D. Pa. July 28, 2016)

well-qualified, based on her decades of experience as a consultant to cosmetic companies, to opine on what a reasonable company would have done in Defendants' position, given the information Defendants had at the time.

In reply, Defendants argue what Plunkett states she will testify about often varies significantly from what she ultimately testifies about. They also reiterate that she is not an FDA expert, and cannot testify regarding the meaning of FDA regulations. Much of Defendants' reply focuses on Plunkett's behavior in other talc trials, where her testimony was admitted. Defendants argue it should not have been permitted, as demonstrated by statements she made at those trials.

IV. ANALYSIS

A. Dr. Plunkett's Causation Opinions At Hearing

Dr. Plunkett reports that she conducted a "safety assessment" for talc based on a "human health risk assessment" in four steps—hazard identification, dose-response assessment, exposure analysis, and characterization of risks. In this regard Dr. Plunkett explained that she used a "weight of the evidence" methodology in defining the hazards of exposure as well as the dose-response relationship.

Secondly, Dr. Plunkett indicated she used the "Bradford Hill" considerations to consider the cause and effect relationship between perineal use of talc and ovarian cancer.

As an initial matter Dr. Plunkett's report, although detailed, does not in fact analyze the issues in terms of a human health risk assessment, per se, although it does analyze the Bradford

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[2] Finding Dr. Plunkett qualified to opine on NSF causation, the stability of Omniscan, and the free gadolinium theory. "She is qualified to interpret the results of any of GEHC's toxicology, pharmacology or pharmacokinetic studies and to opine on the significance of the results. The Court finds that Dr. Plunkett has amply established the methodology underlying her opinions. Dr. Plunkett was also qualified to opine, based on the facts adduced at trial (including GEHC internal studies, documents and regulatory filings), on the accuracy and adequacy of the toxicology, pharmacology and pharmacokinetics data appearing on the Omniscan label at the time the scan(s) in question were administered." *In re Gadolinium-Based Contrast Agents Prods. Liab. Litig.*, 2010 U.S. Dist. LEXIS 43444, *62-63 (N.D. Ohio May 4, 2010)

Hill factors. Much of the Court's thinking about Dr. Plunkett's opinions is contained in the rulings on the other general causation experts, i.e. that they are subject to cross examination but are not excludable. However, at hearing Defendants did show that to a limited extent Dr. Plunkett's conclusions were not supported by the data on which she relied.

In particular, Dr. Plunkett opined that data showed that exposure to talc caused programmed cell death. She relied on a study (Lee, 2010) which she had not read and which in fact showed talc induced the death of lung cancer cells. Similarly, she relied on a study by Nasreen (1978) that showed that talc induced the death of cancer cells but not normal pleural cells.

Plunkett also relied upon a study by Buz'zard et. al. (2007), to say that reactive oxygen species increased over time based on exposure to talc when the data in the study showed a decrease except in one instance. In addition, she contended that this study showed that exposure to talc caused a neoplastic transformation of "normal" ovarian cells but conceded that the cells used in the study were not normal human cells but ones that had been "immortalized", i.e. treated to grow outside the body.

Dr. Plunkett also opined that data showed that talc exposure induces local tissue responses that are adverse, including changes in gene expression which may irreversible, relying on Shukla (2009). She admitted, however, that she had not read the study at the time she wrote her report and that in fact it reported ovarian cells were exposed to talc adapted to its effects. She also acknowledged that the report stated that nonfibrous talc is regarded as nocarcinogenic in humans, although she also noted that in the study the authors did not measure the lack of adaption or the rate of repair and implied that this was because the authors' funding sources did not want such work done.

In addition Dr. Plunkett relied on a National Toxicology Program (NTP) study regarding the effect on rats when talc is inhaled. She acknowledged that after those studies were completed they were evaluated by a task force of regulators, industry members, and scientists, who unanimously concluded the studies could not be considered relevant predictors of human risk, although she contended that other unspecified "minutes" did not support that result.

She also relied on two animal studies (Hamilton 1984) citing them as saying a single injection of talc caused "focal areas of papillary change" when the study said that the papillary

changes were separate from granuloma lesions observed and that there were possible explanations for the papillary changes other than exposure to talc.

In looking at the "weight of the evidence" Dr. Plunkett was aware of studies (Merritt 2008) that were contrary to her opinions but did not indicate in the opinion how she weighed them.

She also opined that the mechanism by which she believes talc causes cancer is by continuous exposure that "overwhelms" the body's normal macrophage immune response. Although she has helped produce a video explaining that phenomena for the jury's consideration, she did not advanced that opinion in her written report but relies on two studies to that effect—Hamilton (2001) and Davies (1983). Hamilton studied arthritis and does not discuss cancer.

B. Rulings Related to Causation

Based on her testimony at hearing it is evident that Dr. Plunkett relied upon some materials that she had not read and that do not stand for the propositions cited (Lee, Nasreen) and relied on others (Buz'zard, Shukla) to support her opinion based on interpretations of the studies which may nor may not be valid. As to the latter, the Court will not exclude her testimony and reliance on the studies. This is an issue that essentially would require the Court to determine "which scientist is right." This the court may not do. However, to the extent Dr. Plunkett intends to offer opinions based on Lee, Nasreen, or any other matters not disclosed in her written report she may not do so. The parties' stipulation required a disclosure of opinions pursuant to state law.

C. **Rulings Related To Labelling and Corporate Behavior**

Dr. Plunkett is also precluded from opining that talc based powders should have been labelled to warn of the risks for two reasons. First, she may not give a legal opinion. *Summers v. A.L. Gilbert Co.* (1999) 69 Cal. App. 4th 1155. Second, although she may have taken courses on FDA matters and give advice on same, she is not qualified to opine as to FDA regulations or their applicability to labeling.

Dr. Plunkett is also precluded from testifying that defendants downplayed the risks of talc and actively determined not to tell consumers of them. This testimony is based solely on reading documents (some of which are admissible notwithstanding hearsay and some of which are not) and then opining as to the mental state of individuals in the corporation. This is not permissible

for two reasons. First, Dr. Plunkett is not qualified to opine as to corporate behavior. She is a pharmacologist. Her expertise is in the realm of science rather than corporate behavior or ethics. Second, expert testimony is not needed on this subject. The jury can be instructed as to applicable law and to the extent otherwise admissible, plaintiff can put in evidence those documents and testimony that show corporate activity and may argue from that. An "expert" is not appropriate.